E. Regulatory Programs

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The regulatory function at TDH is designed to protect the health and safety of all Texans through many programs that relate to the licensing, registration, certification, or permitting of a person, business, or other entity. The programs range from making sure the meat we buy at the grocery store is safe to eat, to ensuring sanitary hotels, to regulating medical practitioners such as radiologic technologists, to inspecting hospitals for safe and hygienic conditions. The regulatory programs are primarily located within two associateships: the Associateship for Environmental and Consumer Health and the Associateship for Health Care Quality and Standards.

These programs have low public visibility until a problem arises. For example, the detection by TDH of large amounts of a harmful algae in the Gulf of Mexico resulted in a ban on consumption of seafood harvested from those coastal waters, thereby heightening the public's awareness of the need for careful inspection of food and water supplies. Another example is the licensing of hospitals and home health facilities, which has become increasingly crucial as the industry grows and the federal government's regulatory role diminishes.

Associateship for Environmental and Consumer Health

Bureau of Food and Drug Safety

Drugs and Medical Devices Division

All drug and medical device manufacturers and wholesale distributors and some limited retail distribution
All drug, medical device, and cosmetic salvage establishments
Tattoo studios
Narcotic treatment programs
Tanning salons

Why regulation is needed

Drug, medical device, and cosmetic regulations are intended to promote the safety and effectiveness of drugs, medical devices, salvaged drugs and devices, and cosmetics manufactured and distributed in Texas. Tattoo regulations are designed to prevent the spread of communicable disease, prohibit underage tattooing, and ensure that tattoo studios are in properly zoned locations. Narcotic treatment program regulations ensure that adequate professional services and controls are applied to programs that use opiates to treat narcotic addiction to safeguard the patient and prevent diversion of opiates outside the treatment setting. Standards for tanning facilities address equipment, client instruction, and operator training to prevent client injury.

Statutory or other requirements for regulating entity

Chapter 431, Health and Safety Code (Texas Food, Drug, and Cosmetic Act): License and regulate all manufacturers, repackers, brokers and distributors of drugs and medical devices to ensure the safety and effectiveness, labeling, advertising of these products, and issue Certificates of Free Sale.

Chapter 432, Health and Safety Code (Texas Food, Drug, Device, and Cosmetic Salvage Act): License and regulate drug, devices, and cosmetic salvage establishments and salvage brokers.

Chapter 439, Health and Safety Code (Manufacture and Distribution of Certain Drugs): Regulate manufacture and distribution of laetrile, dimethyl sulfoxide, and preservation and distribution of certain unused drugs.

Chapter 466, Health and Safety Code (Regulation of Narcotic Drug Treatment Programs): License and regulate narcotic treatment programs.

Chapter 481, Health and Safety Code (Texas Controlled Substances Act): Schedule, reschedule, and deschedule controlled substances.

Chapter 483, Health and Safety Code (Dangerous Drugs): Stipulate who may possess or distribute a dangerous drug. §483.003 and 483.004 allow the Board or Commissioner of Health to limit drugs with the potential to be misused and abused to the prescription of a practitioner.

Chapter 145, Health and Safety Code (Tanning Facilities): License and regulate the operation of tanning facilities.

Chapter 146, Health and Safety Code (Tattoo Studios): License and regulate the operation of tattoo studios.

Scope of and procedures for inspections or audits

Section 431.042, Health and Safety Code, outlines the scope of authority for inspections of drugs, device, and cosmetic factories, warehouses, and transport vehicles. The U.S. Food and Drug Administration's (FDA) *Investigations Operations Manual* contains detailed instruction for conducting inspections and investigations of drug, narcotic treatment program, device and tanning establishments.

Wholesale drug establishments are inspected for proper licensure, sanitation, security, personnel training, complaint files, storage of drugs, inventory, recall, consignor and consignee records, and returned/damaged/out-of-date drugs. In addition, drug manufacturers and repackers are inspected for good manufacturing practices, which include standard operating procedures, equipment, production controls, employee qualifications and training, packaging and labeling controls, laboratory controls, master formulas, and batch records. Frequency of

inspection is based on risk, contract assignment from FDA, compliance history, complaints, and prior inspections.

Medical device manufacturing firms are inspected for licensure, good manufacturing practices, quality assurance, control of critical components, quality audits, production and process controls, reprocessing, records, and labeling and complaint files. Inspection frequency is based on risk contract assignments from FDA, compliance history, complaints, and prior inspections.

Tattoo studios are inspected for compliance with Drugs and Medical Devices Division (DMDD) regulations and local building and zoning codes before a license may be issued. Inspection includes examination of studio for required client records, sanitation, aseptic techniques and practices, sterilization of equipment, disposal of infectious waste, tattoo care instructions, and reporting of adverse reactions to tattooing. In addition to pre-licensure inspections and complaint investigations, the goal is to inspect tattoo studios annually.

Narcotic treatment programs are inspected for compliance with state and federal regulations requiring documentation of patient's progress or lack of progress in treatment. Records examined include but are not limited to: minimum standards for admission, dosing records, take-home medication requirements, special treatment for pregnant patients, treatment plans and counseling records, required urine screens for illicit drugs, staffing patterns, HIV counseling, and screening tests for tuberculosis. Frequency of inspections depend upon compliance history and complaints; however, biennial inspections are the goal.

Tanning facility inspections are based on compliance history and complaints. They are inspected for licensure, sanitation, compliant tanning devices, required warning signs, use of protective eyewear, presence of trained operator, client instructions and records, and reporting requirements for injury.

During fiscal year 1996, 2,515 firms were inspected from an inventory of 4,943 firms (51%).

Follow-up activities when non-compliance is identified

DMDD response to non-compliance depends on the severity of the violation and its relative threat to public health. Generally, a warning letter is issued to the firm within 30 days of the inspection requiring the firm's written response detailing corrective action it will take. If the corrective action is insufficient or incomplete, another letter is sent to the firm for further written response. If a subsequent inspection reveals continued non-compliance, a second warning letter is issued, requiring a written response. A third non-compliant inspection usually results in an invitation to the firm for a "compliance meeting" between DMDD and

the firm in lieu of assessing administrative penalties. If the firm declines the meeting, administrative penalties are assessed. At the meeting, the firm is given a short period to prepare and submit to DMDD a plan that details how compliance will be achieved. Continued non-compliance may result in assessment of administrative penalties or revocation of license.

Imminent health hazards are followed with streamlined degrees of response that may include immediate action up to an emergency order under Chapter 431 Section 431.045 or injunctive relief pursuant to Section 431.047 for violations of Section 431.021 entitled Prohibited Acts.

Follow-up to contract inspections is planned in cooperation with FDA.

Sanctions available to ensure compliance

Section 431.054 administrative penalties not to exceed $25,000 per day for each violation may be assessed against a person who violates Section 431.021 entitled Prohibited Acts or an order adopted or registration issued. Tattoo studios may be assessed administrative penalties not to exceed $5,000 per day for each violation pursuant to Chapter 146, Section 146.019 of the Texas Health and Safety Code.

Civil penalties not to exceed $25,000 per day for each violation may be assessed against a person who has violated Section 431.021 and up to $10,000 for each violation for narcotic treatment programs under Chapter 466, Section 466.043.

Section 431.059(a) provides that a person who violates Section 431.021 commits a Class A misdemeanor and a Class C misdemeanor for tattoo studios under Chapter 146, Section 146.018.

Civil injunctions are available for drug, device, salvage and tanning facilities that violate Section 431.021.

Administrative actions include revocation, cancellation, suspension, and probation of a license as well as emergency orders and detention of adulterated and/or misbranded drugs or devices.

Recall and condemnation authority exists for drugs and devices under Chapter 431, Sections 431.048 and 431.0495.

Procedures for handling consumer/public complaints against regulated entities

Upon receipt, available complaint information is documented on a Complaint/Injury Report form, assigned a complaint number, and entered into the complaint database. The complaint form is forwarded to a supervisor for review to determine if an investigation is warranted. Complaints not investigated are deemed "closed."

Active complaints are assigned to an investigator to gather additional information, or if appropriate, the complaint is referred to an agency with jurisdictional authority. After the investigation is complete, a Report of Investigation is reviewed by the supervisor to determine what action, if any, is appropriate. After appropriate action is taken, the status of the complaint investigation is then "closed" in the computer database.

Manufactured Foods Division

All food manufacturers and wholesale distributors

Why regulation is needed

Regulation of these industries is needed to assure the citizens of Texas a supply of safe, wholesome, properly labeled foods and that foods that are truthfully presented. As with other food safety programs, regular inspections of food manufacturers and wholesale distributors helps to reduce the risk of food-borne diseases caused by *E. Coli* O157:H7, *Salmonella,* and other pathogens. TDH conducts 95 % of all inspections of these entities, with the exception of the U.S. Food and Drug Administration (which conducts fewer than 100 food inspections in Texas in any given year), no other agency exists to assure the safety of foods presented for sale in this state.

Statutory or other requirements for regulating entity

Chapter 431, Health and Safety Code (Texas Food, Drug, and Cosmetic Act): License and regulate all food manufacturers, wholesale food distributors, and food retailers engaged in food processing to ensure safety and proper labeling and advertising of food products.

Chapter 432, Health and Safety Code (Food, Drug, Device, and Cosmetic Salvage Act): License and regulate all food salvage establishments, (including the distribution of salvaged products) to ensure safety and proper labeling and advertising of food products.

Chapter 434, Health and Safety Code (Public Health Provisions Relating to Production of Baked Goods): Regulate of all baked goods, including net weight and sanitation of premises where products are manufactured.

Chapter 438, Health and Safety Code (Public Health Measures Relating to Food): License and regulate establishments dispensing bulk foods.

Scope of and procedures for inspections or audits

The scope of inspections includes the premises where the commodities are manufactured and stored, transportation vehicles used, raw ingredients received, the production of the commodities, packaging and labeling, fill of the containers, and integrity of certain hermetically sealed containers. The inspections also include a review of the products to determine if fraudulent practices have been involved, such as substituting an inferior ingredient for a more expensive ingredient such as the use of yellow food coloring instead of butter) and whether the establishment is properly licensed.

Inspection of the premises involves examination of plant sanitation, including handling of ingredients and cleanliness of processing equipment; employee hygiene and health; source of water used; pesticides and/or sanitizers used; rodent and insect control measures; building construction; refrigeration (if required); net weight; labeling (ingredients, nutrition labeling, health claims, common or usual name of product, compliance with standard of identity for certain commodities); safety of packaging materials; and transportation practices.

Various rules have been adopted under Health and Safety Code Chapters 431 and 432 to aid in the enforcement of these laws. Certain federal regulations also have been adopted by reference under Section 431.244 of Chapter 431 including the Good Manufacturing Practice Regulations contained in 21 Code of Federal Regulations Part 110, Sections 110.3-110.110.

Numbers of establishments inspections performed FY 1996: 5,689.
Percentage of total inventory inspected in FY 1996: 37.9%*
Percentage of establishments (other than vended water operations) inspected in FY 1996: 46.4%

*NOTE: 2,768 of the licenses issued are for vended water operations, which do not require routine inspection.

Follow-up activities when non-compliance is identified

The Manufactured Foods Division uses a "risk assessment module" to determine the reinspection frequency of an establishment. One factor in the module is whether the firm has a history of non-compliance. Consequently, a reinspection may occur as soon as a week or a month following inspection, based upon the severity of the violations.

The division also uses "warning letters" to establishments found to be out of compliance. These letters request that management notify the division in writing of voluntary corrective actions taken within 15 days of receipt of the letters. Letters are generally issued within 30 days of the completion of the inspection. During reinspection of the establishment, field investigators report the numbers and types of voluntary corrective actions made since the previous inspection.

Section 431.048 of the Texas Health and Safety Code grants the division detention, or embargo power, preventing an establishment from using, selling, or otherwise distributing a severely misbranded or adulterated commodity. If the commodity can be reconditioned to bring it into compliance (i.e. relabeling or cleaning), the establishment is given the opportunity to do so. Otherwise, the commodity is either voluntarily destroyed or destroyed upon order of the court.

Sanctions available to ensure compliance

Section 431.054 authorizes administrative penalties of up to $25,000 a day per violation to be assessed against a person who violates Section

431.021 (Prohibited Acts), an order adopted by the Commissioner of Health, or conditions of the license.

A violation of the law is a Class A misdemeanor. Action may be taken against a violator in a County or District Court under Section 431.059(a).

Under Section 431.0585, civil penalties of up to $25,000 a day for each violation may be assessed after a referral to the Attorney General, City Attorney, or District Attorney.

The division may, through administrative procedures, deny, suspend, or revoke a license issued under either Chapter 431 or Chapter 432. These procedures are contained in 25 Texas Administrative Code Chapter 229.

Detention or embargo authority is described above.

Emergency Order issued by the Commissioner of Health is available under Section 431.045.

Temporary Restraining Order, Temporary Injunction, and/or Permanent Injunction sought by the Attorney General on behalf of TDH, including recovery of costs incurred is available pursuant to Section 431.047.

Condemnation of detained or embargoed article is authorized under Section 431.053.

Recall of adulterated, contaminated, or severely misbranded articles is available under Section 431.0495.

Procedures for handling complaints against regulated entities

The Manufactured Foods Division follows procedures established by the Bureau of Food and Drug Safety for the investigation of complaints against regulated industry. This policy includes completion of all complaints of a public health significance within 30 days. Complaints indicating an injury or illness are investigated within 24 hours. All other complaints are investigated during the next routine (or compliance) inspection of the regulated establishment.

Complaints related to an establishment regulated by this division are recorded in writing, with or without the complainant's name, address, and telephone number. Complaints taken by the Austin headquarters are forwarded to the appropriate public health region for investigation, with a copy held in the Austin headquarters to match with a completed investigation later. Complaints taken at the regional level are investigated per established protocol (see above), with a completed Inspection Report submitted to the Austin headquarters for evaluation. If a complainant leaves a name and telephone number with the division, the complainant is notified by phone of the investigation results. The division uses the regulatory options available in evaluating the complaint with respect to

further action that may be needed (warning letters included). Information on completed complaints is entered in a complaint database.

Complaints received against establishments which are not regulated by this division are either forwarded to the responsible division or to local authorities with jurisdiction in the matter.

Meat Safety Assurance Division

State inspected meat and poultry packing plants

Why regulation is needed

Food-borne illnesses, especially those caused by emerging pathogens, often are linked to microorganisms that originate in food animals from which the meat or poultry was derived. Among other sources of causative agents for food-borne illness are pathogens that have become resident in processing plants and poor food handling or personal hygiene practices that lead to product cross contamination. One example of a food-borne disease outbreak related to meat products is the recent outbreak of *E. coli* O157:H7 linked to hamburger patties processed at a Nebraska meat packing plant.

Regulatory standards have evolved in an effort to deal with these and other elements of a changing industry and the dynamic spectrum of microbiological threats. A regulatory presence is needed in production facilities to assure that regulatory standards are met, thereby assuring that only wholesome meat and poultry products are allowed to enter commerce. The Federal Meat Inspection Act (21 U.S.C., sec. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C., sec. 451 *et seq.*) require meat and poultry be inspected by either federal or state meat and poultry inspection program. State programs such as Meat Safety Assurance (MSA) are more responsive to the small, family-owned and run establishments that comprise the vast majority of plants under state inspection. The regulated industry is better served, and the health of the communities supplied by it is enhanced.

Statutory or other requirements for regulating the entity

Chapter 433, Health and Safety Code (Texas Meat and Poultry Inspection Act (TMPIA)) authorizes TDH's meat safety assurance program. The Federal Meat Inspection Act and Poultry Products Inspection Act require all meat and poultry products moving in commerce to be inspected and require states to establish mandatory meat and poultry inspection programs, otherwise federal inspection is imposed.

Chapter 144, Health and Safety Code (Texas Renderers' Licensing Act (TRLA) authorizes TDH to license and inspect rendering firms.

Scope of and procedures for inspections or audits

Livestock slaughtered for intrastate sale must receive ante-mortem and post-mortem inspection by inspectors appointed by the Commissioner of Health. Meat, poultry, and associated products for intrastate sale must be prepared under continuous inspection by a TDH inspector to ensure

products are unadulterated, properly labeled, and stored in a manner that prevents adulteration. Establishments where livestock are slaughtered and meat and poultry are processed are continuously inspected for sanitation, using a computer-generated Performance Based Inspection System (PBIS). In FY 1996, MSA provided continuous inspection services to all 368 establishments with a grant of inspection. The program also reviewed all 146 establishments operating under a grant of Custom Exemption (CE). The minimum frequency of CE reviews is quarterly.

On ante-mortem inspection, an MSA inspector evaluates all animals presented for slaughter to determine if each is within normal limits and eligible for slaughter. If determined to be other than normal, the inspector will designate the animal "Suspect" and segregate the animal in a suspect pen until an MSA veterinarian can evaluate the animal's eligibility for slaughter. The veterinarian may declare the animal eligible for routine slaughter, declare the animal eligible for slaughter as a suspect, or condemn the animal on ante-mortem. The handling of animals on the inspected premises, up to and including the stunning process, is evaluated by the inspector to assure that humane handling practices are followed.

After stunning, the inspector observes plant employees' procedures to assure good manufacturing practices are followed and regulatory standards met. The inspector will follow accepted protocol in incising, palpating, and otherwise inspecting organs and tissues to assure that no adulterated material is imprinted with the mark of inspection. The inspector further assures that all such adulterated or inedible material is denatured and routed to a location approved by the Texas Animal Health Commission to preclude its diversion to the human food chain.

Through the PBIS system, MSA inspectors evaluate facilities and procedures used by the establishment to determine whether they meet regulatory standards. Furthermore, the inspector determines whether the establishment's management has shouldered its ultimate responsibility for producing a wholesome product. This will be determined in part by assessing whether the establishment is following its Sanitation Standard Operating Procedure (SSOP) in both implementation and documentation.

TDH inspects 100% of the 128 rendering business licensees (haulers and/or processors of rendering materials, including waste grease) at least once each calendar year or more often when necessary to assure compliance with all requirements. TDH inspectors ensure that rendering businesses and vehicles maintain adequate facilities and sanitation to safely dispose of dead animals, inedible animal materials, and waste grease to preclude the spread of disease and control odors.

Follow-up activities when non-compliance is identified

When a deficiency is identified, the inspector retains affected product and annotates the findings on a Process Deficiency Record (PDR). The PDR is presented to the designated plant contact person with the expectation of

a timely response as to both corrective actions and preventive measures to be employed. If the proposal is acceptable to the inspector, implementation is verified and documented with subsequent "closure" of the PDR. In the absence of appropriate action by plant management and inspector verification, as described above, the PDR remains "open." Operations that fail to correct and prevent deficiencies, or those found to have non-SSOP repetitive deficiencies, are placed on Intensified Inspection Procedures (IIP). Repetitive SSOP failures due to the same root cause may result in withholding of inspection services.

Failure of plant employees to handle animals humanely results in the inspector rejecting the area or equipment involved in the violation. The area or equipment will remain rejected until plant authorities propose and commit to follow an action plan that alleviates the problem.

All complaints related to meat and poultry products or to rendering by the general public, other state programs, or other entities are investigated. All deficiencies noted are documented and followed up with a letter of warning or notice of intent to propose administrative penalty depending on the violation and repetitiveness of the violation. Firms or individuals that are found to be in violation of TMPIA or TRLA are placed on an intensified compliance program.

Sanctions available to ensure compliance

If compliance cannot be achieved, the grant of inspection is withdrawn, following established procedures that allow for a formal hearing, and the firm can no longer produce products for intrastate commerce. Firms and individuals violating the TMPIA are subject to administrative penalties.

Firms and individuals continuing to violate the TRLA are subject to administrative penalties as provided for by Chapter 144, Health and Safety Code. All administrative penalties collected go to the general fund.

Procedures for handling complaints against regulated entities

Complaints against an entity operating under a grant of inspection or custom exemption are assigned a number, logged for tracking purposes, and forwarded to the MSA Regional Program Manager of the region in which the entity is located. The Regional Program Manager uses the resources and documentation at his/her disposal, coupled with acquired information deemed germane to the issue at hand, to arrive at a decision as to the existence of a violation.

Complaints against entities subject to regulation, but not in the MSA program are directed to the MSA Program Manager for Compliance. The complaint is assigned to a compliance officer for investigation. The officer will secure from the illicitly operating entity a letter stating that the entity will alter operations to eliminate additional violations, or request a survey by regional MSA personnel with the intention of acquiring an grant of inspection.

All violations are reported to the MSA division director for appropriate additional action which may included one or more of the following:

- Letter of warning;
- Administrative penalty;
- Intensified Inspection Procedures;
- Suspension of inspection services;
- Initiation of procedures to withdraw grant;

TDH policies affording the alleged violator due process are followed at all times.

Milk and Dairy Products Division

Milk and dairy products

Why regulation is needed

Regulation of milk, milk products, and frozen desserts is essential to protect consumers from diseases or other health threats which are potentially transmitted by these products. This regulation is also necessary for Texas to comply with the Interstate Milk Shippers Agreement which allows the Texas milk industry to continue to: (1) sell their products outside of Texas; (2) enter into federal contracts to supply milk to veterans' hospitals and military installations; and (3) participate in the National School Lunch and National School Breakfast programs.

Statutory or other requirements for regulating the entity

Chapter 435, Health and Safety Code (Dairy Products) and Chapter 440, Health and Safety Code (Frozen Dessert Manufacturer Licensing Act): Provides TDH with specific statutory authority to regulate milk, milk products, and frozen desserts produced, processed, or manufactured in Texas or imported from other states. State law has provided for the regulation of milk in Texas since 1937. Until 1979, cities had the primary role of inspecting and regulating dairies with TDH oversight. In 1979, state law authorized statewide regulations for the safety of milk and milk products, giving regulatory responsibility to TDH.

Chapter 431, Health and Safety Code (Texas Food, Drug and Cosmetic Act): Provides general authority to regulate food, including milk, milk products, and frozen desserts.

Texas participates in the Interstate Milk Shippers Agreement which sets standards for the interstate commerce for these products based on the following federal regulations and guidelines:

- U.S. Public Health Service (USPHS)/FDA Recommended Grade A Pasteurized Milk Ordinance;
- Grade A Raw For Retail Milk Regulation;
- USPHS/FDA Dry Milk Ordinance;
- USPHS/FDA Rules For the Manufacture of Single Service Containers and Closures;
- FDA Food Manufacturing Rules for Manufactured Milk Products;
- U.S. Department of Agriculture Manufacture of Milk Products.

Scope of and procedures for inspections or audits

State regulations ensure the safety of the state's milk supply through a program of permitting and inspecting dairies and milk processing plants. TDH regulations provide specifications for producing, handling, and labeling milk that ensure the safety and food value of milk as well as sanitary conditions. TDH sanitarians survey and inspect these facilities periodically to certify their compliance with state standards. TDH also uses product sampling and lab analysis to evaluate the milk for contamination and butterfat content. Milk that does not qualify as Grade A or is found to contain contaminants such as antibiotics cannot be sold for human consumption in Texas. Dairies whose milk does not pass the laboratory analysis cannot sell milk until follow-up laboratory analysis proves the milk to be safe.

In FY 1996, the Milk and Dairy Products Division (MDPD) performed 72,275 surveillance activities on 2,419 permitted facilities. The majority of these activities were sample collections required by the Grade A Pasteurized Milk Ordinance. This Ordinance also specifies the frequency of inspection for each type of facility. In 1996, MDPD performed 8,315 inspections on the 2,419 permitted establishments in order to meet those frequency of inspection requirements.

Follow-up activities when non-compliance is identified

When conditions at a milk processing plant, bulk milk transport tanker, producer dairy, retail raw milk dairy, frozen dessert manufacturing plant, milk condensing plant, milk drying plant, or transfer/receiving plant are below state standards, TDH has a variety of follow-up activities and sanctions to ensure compliance. TDH may reinspect the facility/operation more frequently or warn the facility/operation and impose a time limit for correction. Depending on the severity of the violation, TDH may also retain products processed, manufactured, or transported by the facility/operation; begin condemnation proceedings of the product in question; suspend the permit of the facility/operation; seek a revocation hearing; or seek administrative penalties.

Sanctions available to ensure compliance

If a warning has been given to the facility/operation and a specific time limit imposed, the sanitarian will reinspect the facility/operation and either confirm that corrections have been made, confirm that they have not been made, suspend the permit if conditions warrant, reinstate warning, or remove all sanctions. Repeated permit suspensions are cause to convene a hearing for permit revocation.

Procedures for handling complaints against regulated entities

MDPD has both a complaint and enforcement process. Complaints usually originate from consumers of milk or frozen dessert products, citizens living near a producer dairy farm or milk plant, or from other agencies. Examples of consumer complaints include hydrocarbon or other chemical odor or flavor in milk in returnable plastic jugs, milk that goes bad shortly after purchase and before the lapse of the coded pull-date, and unclean milk cases used for milk delivery at markets, schools, or institutions. Examples of complaints from citizens living near a producer

dairy farm include odor from cowyards at producer dairy farms, flies generated by fly breeding in manure or other harborage around producer dairy farms, and unsightliness of appearance of the surroundings on a producer dairy farm not properly maintained. Other agencies that may submit complaints include the Texas Natural Resources Conservation Commission (complaining that a producer dairy farm is draining semi-liquid wastes into a river, creek, lake or other tributary); the U.S. Food and Drug Administration (complaining that illegal or mislabeled milk products are being offered for sale within the state of Texas).

In all instances, complaints are investigated by either Austin headquarters staff or public health regional sanitarians. If, upon careful investigation including both on-site inspection of the alleged violative or objectionable condition and consultation with the operator, it is determined sufficient cause exists for action, several alternatives are available as penalties. The sanitarian may, if any imminent health hazard does not exist but a violation of the requirements of either the Texas Milk Grading and Labeling Law or Texas Frozen Dessert Manufacturer Licensing Act does exist, issue a written warning to the permittee and impose a specific time frame for correction imposed. If an imminent health hazard does exist, the Texas Grade A milk permit or Texas Frozen Dessert Manufacturer License may be suspended, misdemeanor charges may be brought in the appropriate court, and, in certain incidences of repeated violations, a hearing process to revoke a permit or license. If no violation is found, a report to that effect is completed by the investigating sanitarian. Should the violative condition represent a threat to the health of the community, public notification will occur by print and electronic media through the offices of TDH's Health Promotion Division. Public service announcements by print and electronic media have informed the public adequately of the agencies to which complaints should be addressed.

Retail Foods Division

All retail food establishments not under local inspection

Why regulation is needed

This program is needed to assure that all retail food establishments in the state are under routine inspection to protect the general public from food-borne illness. Chapter 437 of the Texas Health and Safety Code mandates that TDH permit and inspect all food service establishments, retail food stores, mobile food units, and roadside food vendors in any area of the state which is not inspected by local governments.

Statutory or other requirements for regulating the entity

Chapter 437, Health and Safety Code (Regulation of Food Service Establishments, Retail Food Stores, Mobile Food Units, and Roadside Vendors): Requires TDH to permit and inspect retail food establishments not under local jurisdiction.

Scope of and procedures for inspections or audits

An Inspection Frequency Analysis (food safety risk-based assessment) is conducted during all initial inspections to prioritize inspections based on the level of risk of the establishment. Establishments are inspected using a

Hazard Analysis Critical Control Point (HACCP) focus. HACCP is a scientifically proven food safety methodology of inspecting food operations.

This inspection method focuses on critical items that, if left uncontrolled, may lead to conditions that may result in a food-borne illness outbreak. In FY 1996, field staff conducted 5,339 inspections of the 14,316 retail food facilities which are under TDH's permitting jurisdiction.

Follow-up activities when non-compliance is identified

Retail food establishments that do not meet minimum inspection standards are sent a warning letter advising the operator that the establishment does not meet minimum state standards. A re-inspection of the establishment is conducted 30 days later. A second warning letter is sent if the establishment does not show satisfactory improvements on re-inspection. Evidence is collected during the re-inspection if satisfactory improvements are not made. Additional documentation such as pictures and samples are collected to support the findings. A third inspection is conducted to determine final compliance status of establishments not meeting minimum state standards on re-inspection.

Enforcement actions such as administrative penalties are initiated if the establishment does not meet minimum state standards after the third inspection. In cases where an establishment presents an imminent health hazard to the consumer, voluntary closure is sought. If the establishment refuses to close voluntarily, a court order or injunction may be obtained. Imminent health hazards are acted on immediately and are not subject to the warning letter provision.

Sanctions available to ensure compliance

TDH may use one of these three enforcement sanctions against an establishment that has not met minimum state standards:

- Injunctive relief under Section 437.015;
- Criminal penalties under Section 437.016;
- Administrative penalties pursuant to Title 25 Texas Administrative Code (TAC) section 229.261(a), entitled Assessment of Administrative or Civil Penalties.

Procedures for handling complaints

Investigation of consumer complaints is a priority for the Retail Foods Division. Complaints involving an imminent health hazard are investigated immediately, not to exceed 24 hours from time of receipt. Examples are those that include alleged food-borne illness or injury reported by consumers or physicians. Other complaints of a less serious nature are investigated within 30 days and are combined with routine field work to assure travel efficiency. All complaints result in a retail food inspection. When violations are disclosed as a result of the inspection, regulatory actions (such as establishment of compliance schedules) are implemented. Follow up inspections are also conducted to assure compliance.